

REMARKSI. Introduction

In response to the Office Action dated June 1, 2005, claims 23, 41, 89, 106 and 123 have been amended and claims 140-144 have been added. Claims 23-58 and 83-144 remain in the application. Entry of these amendments, and re-consideration of the application, as amended, is requested.

II. Claim Amendments

Applicants' attorney has made amendments to the claims as indicated above. These amendments are fully supported by the specification as filed and introduce no new matter.

III. Non-Art Rejections

On page (2) of the Office Action, claims 23, 41, 89, 106, and 123 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite, with the Patent Office asserting that the term "compact" does not provide any structural limitation to facilitate being carried by a user.

While Applicants respectfully traverse this rejection because the disclosure (e.g. paragraph [0004] of the specification) does allow artisans to understand the structural limitations of this term, Applicants have nonetheless amended claims 23, 41, 89, 106 and 123 to remove this language and overcome this rejection.

New dependent claims 140-143 have been added to encompass embodiments of the invention where a structural limitation that facilitates the invention being carried by a user is clearly recited. These embodiments are described in detail in U.S. Patent No. 6,554,798 (e.g. at column 32, lines 33-64), a document whose contents were expressly incorporated by reference (e.g. in paragraph [0003] of the specification). For purposes of clarity and in accordance with the provisions of M.P.E.P. 608.01(p), the specification has been amended to include the material incorporated by reference.

IV. Prior Art Rejections

On pages (2)-(4) of the Office Action, claims 23 and 41 were rejected under 35 U.S.C. §102(b) as being anticipated by Orkin et al. (Orkin), U.S. Patent No. 5,207,642. On pages (4)-(5) of

the Office Action, claims 24-40, 42-58, and 83-135 were rejected under 35 U.S.C. §103(a) as being unpatentable in view of the combination of Orkin, and/or Kerns et al. (Kerns), U.S. Patent No. 4,756,706, Lebel et al. (Lebel1), U.S. Patent No. 6,562,001, Lebel et al. (Lebel2), U.S. Patent No. 6,810,290, and Rodler, U.S. Patent No. 4,457,751.

In the sections below, Applicants review the invention recited in the amended claims and respond to the Examiner's rejections of the claims presented in Applicants' response to the last Office Action.

A. The Claimed Invention

Applicants' specification teaches that embodiments of the invention are directed to infusion systems and methods that are used to deliver medication to a user in precisely controllable manner, for example to deliver insulin to a individual who suffers from diabetes. Such very precise drug delivery schemes can be crucial for the management of chronic diseases. For example, the administration of insulin in a manner that mimics the fluctuating levels this molecule that are observed in healthy individuals (e.g. in response to meals etc.) will significantly reduce the morbidity and mortality issues associated with this chronic disease. In this context, embodiments of the invention recited in the amended claimed are directed to optimized therapeutic regimens, ones for example that allow diabetics to simultaneously administer insulin according to: (1) a first delivery profile such as one designed to mimic the physiological basal levels of insulin that are observed in vivo; and (2) a second delivery profile such as one designed to mimic the fluctuating levels of insulin that are observed in vivo in response to meals (e.g. a bolus) etc. The invention recited in the amended claims allows user to selectively control one or more of these simultaneous administration profiles.

In response to the outstanding office action the claims have been amended to clearly recite this system for delivering a medication, one designed to simultaneously administer a therapeutic molecules such as insulin from a single medication reservoir according to a plurality of medication delivery profiles. In this context, the claims further recite a medication system that includes a plurality of suspend functions capable of separately suspending at least one of the plurality of medication delivery profiles so that a user can suspend a first delivery profile that delivers a medication from the medication reservoir to a user (e.g. a delivery profile such as a meal bolus) while

a second delivery profile continues to deliver a medication from the medication reservoir to a user (e.g. a delivery profile such as a basal rate of administration). Such systems, which allow the simultaneous delivery of a molecule such as insulin from a single reservoir via multiple delivery profiles provides significant health benefits to a user because they allow a user to administer a therapeutic molecule such as insulin according to a schedule that closely mimics the fluctuating daily levels this molecule that are observed in healthy individuals.

B. Rejection under 35 U.S.C. §102(b)

On page (3) of the Office Action, claims 23 and 41 were rejected under 35 U.S.C. §102(b) as being anticipated by Orkin et al., U.S. Patent No. 5,207,642 (Orkin).

Applicants respectfully traverse this rejection because Orkin fails to teach or suggest systems and/or methods for delivering medication as recited in the amended claims, for example a system that includes a control system having an algorithm for controlling medication delivery by the infusion pump so that a user can suspend a first delivery profile that delivers a medication from the medication reservoir to a user while a second delivery profile continues to deliver a medication from the medication reservoir to the user. Instead, Orkin merely teaches a medication delivery system in the form of a mobile hospital cart having a framework designed to accommodate hanging IV bags filled with fluid medications. These hanging medication bags are coupled to tubes that are then controlled by electrically actuated clamps or tubing occluders designed to modulate fluid flow. Because of the differences in the design of the system disclosed in Orkin, this reference fails to teach or suggest Applicants' invention, i.e. a drug delivery system that includes a control system having an algorithm for controlling medication delivery, one that controls a single reservoir and is capable of delivering multiple medication profiles of the same medication at the same time from the same reservoir (i.e. as recited in the underlined text immediately above). In addition, Orkin fails not only to teach or suggest a system designed to deliver varying rates of the same medication at the same time but further fails to teach or suggest a system that can also selectively suspend one or more of the plurality of medication delivery profiles according to physiological need (e.g. as recited in claim 23).

Because Orkin fails to teach or suggest a system designed to simultaneously deliver the same medication according to different drug delivery profiles (e.g. a basal and bolus profile), this reference

cannot anticipate the claimed invention. In addition, Orkin further fails to anticipate the invention recited in the amended claims because this reference further fails to teach or suggest a system designed to simultaneously deliver the same medication and, in addition, one that allows a user to selectively suspend one or more of these plurality of medication delivery profiles. For these reasons, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §102(b). In particular, as noted for example in M.P.E.P. 2131, a claim is anticipated only if each and every element as set forth in the claim is found in a single art reference. As Orkin fails to teach for example a system designed to simultaneously deliver a medication from a medication reservoir to a user using two multiple delivery profiles, this disclosure cannot anticipate the claimed subject matter.

In addition, a comparison of the system disclosed in Orkin and the claimed invention shows that substantial modifications are required to reorganize the Orkin hanging IV cart system in a manner that would generate a system for delivering medication that includes a control system having an algorithm for controlling medication delivery by the infusion pump so that a user can suspend a first delivery profile that delivers a medication from the medication reservoir to a user while a second delivery profile continues to deliver a medication from the medication reservoir to a user (if this is even possible). However, Orkin fails to provide a teaching on how this would be accomplished or even a motivation to modify their system in this manner. Consequently, this reference cannot be used to render the claimed invention obvious. In particular, obviousness can only be established by combining, modifying the teaching of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. M.P.E.P. 2143.01, *In re Fine*, 5 USPQ 2d 1596 (Fed. Cir. 1988). For this reason, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a).

C. Rejections under 35 U.S.C. §103(a)

On page (4) of the Office Action, claims 24-40, 42-58 and 83-135 were rejected under 35 U.S.C. §103(a) as being unpatentable over Orkin and/or Kerns et al., U.S. Patent No. 4,756,706 (Kerns) in view of Lebel et al., U.S. Patent No. 6,562,001 (Lebel1), Lebel et al., U.S. Patent No. 6,810,290 (Lebel2) and further in view of Rodler, U.S. Patent No. 4,457,751 (Rodler).

Applicants respectfully traverse the rejection under 35 U.S.C. §103(a) as being unpatentable over Orkin for the reasons noted above.

Applicants respectfully traverse the rejection under 35 U.S.C. §103(a) as being unpatentable over Kerns because this reference also fails to teach or suggest systems and/or methods for delivering medication as recited in the amended claims, for example a system that includes a control system having an algorithm for controlling medication delivery by the infusion pump so that a user can suspend a first delivery profile that delivers a medication from the medication reservoir to a user while a second delivery profile continues to deliver a medication from the medication reservoir to a user.

Similar to the Orkin disclosure, Kerns merely teaches a medication delivery system in the form of a mobile hospital cart having a framework designed to accommodate hanging IV bags filled with fluid medications. Kerns teaches a medication delivery system which utilizes hanging IV bags filled with fluid medications (see, e.g. column 2, lines 45-48 and FIG. 1). In addition, Kerns explicitly teaches that the invention is a modular system in which the hanging IV bags, pumps and monitoring modules can be selectively attached, both physically and electrically, to a central management unit. This central management unit then controls the internal setup of all modules attached to it, and receives and displays information from them. Each of the modules is capable of being detached from the central management unit, and while so detached is capable of operating independently for an extended period of time. See, e.g. the Kerns specification at column 1, lines 40-50.

Like Orkin, Kerns this reference fails to teach or suggest Applicants' invention, i.e. a drug delivery system that includes a control system having an algorithm for controlling medication delivery, one that controls a single reservoir and is capable of delivering varying medication profiles of the same medication at the same time. In addition, Kerns fails not only to teach or suggest a system designed to deliver varying rates of the same medication at the same time but also one that can selectively suspend one or more of the plurality of medication delivery profiles according to physiological need (e.g. as recited in claim 23). Consequently the Kerns and Orkin disclosures cannot alone, or in combination, be used to generate the claimed invention.

In addition, a comparison of the system disclosed in Kerns and the claimed invention shows that substantial modifications are required to reorganize the Kerns IV cart system in a manner that would generate a system for delivering medication that includes a control system having an algorithm for controlling medication delivery by the infusion pump so that a user can suspend a first

delivery profile that delivers a medication from the medication reservoir to a user while a second delivery profile continues to deliver a medication from the medication reservoir to a user (if this is even possible). However, Kerns fails to provide a teaching on how this would be accomplished or even a motivation to modify their system in this manner. Consequently, this reference cannot be used to render the claimed invention obvious. In particular, obviousness can only be established by combining, modifying the teaching of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. M.P.E.P. 2143.01, *In re Fine*, 5 USPQ 2d 1596 (Fed. Cir. 1988). For this reason, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a) in view of the Orkin and/or Kerns disclosures.

Applicants respectfully traverse the rejection under 35 U.S.C. §103(a) in view of the Orkin and/or Kerns disclosures in combination with Lebel1, Lebel2 and Rodler references because Lebel1, Lebel2 and Rodler fail to remedy the deficiencies of the Orkin and Kerns references. In particular, like Orkin, the Kerns, Lebel1, Lebel2 and Rodler references either alone or in combination fail to teach or suggest systems and/or methods for delivering medication as recited in the amended claims, for example a system that includes a control system having an algorithm for controlling medication delivery by the infusion pump so that a user can suspend a first delivery profile that delivers a medication from the medication reservoir to a user while a second delivery profile continues to deliver a medication from the medication reservoir to a user. A review of the Lebel1, Lebel2, and Rodler references shows that the disclosures in these patents fail to overcome the deficiencies in the Orkin and Kerns disclosures (which is understandable as they are cited by the Examiner merely in view of the basal, square wave and dual wave profiles recited in the pending claims). Consequently, a combination of the disclosures in the Orkin and/or Kerns in view of Lebel1, Lebel2, and Rodler cannot be used to generate the claimed invention. For this reason, Applicants respectfully request the withdrawal of the rejections under 35 U.S.C. §103(a).

Moreover, the various elements of Applicants' claimed invention together provide operational advantages over Orkin, Kerns, Lebel1, Lebel2, and Rodler. In addition, Applicants' invention solves problems not recognized by Orkin, Kerns, Lebel1, Lebel2, and Rodler. Thus, Applicants submit that independent claims 23, 41, 89, 106, and 123 are allowable over Orkin, Kerns, Lebel1, Lebel2, and Rodler. Further, dependent claims 24-40, 42-58, 83-88, 90-105, 107-122, and

124-139 are submitted to be allowable over Orkin, Kerns, Lebel1, Lebel2, and Rodler in the same manner, because they are dependent on independent claims 23, 41, 89, 106, 123, respectively, and thus contain all the limitations of the independent claims. In addition, dependent claims 24-40, 42-58, 83-88, 90-105, 107-122, and 124-139 recite additional novel elements not shown by Orkin, Kerns, Lebel1, Lebel2, and Rodler.

V. Conclusion

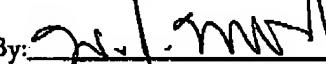
In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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